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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,843	03/30/2001	Samir Kumar Brahmachari	Q63915	7045

7590 12/22/2005

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WASHINGTON, DC 20037-3213

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/820,843

Applicant(s)

BRAHMACHARI ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-24, 26-30, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-24, 26-30, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 9/6/05, has been entered.

Amended claim 20, filed 9/6/05, is acknowledged.

Claims herein under examination are 20-24, 26-30, and 32-33.

### ***Claim Objections***

Claim 20 is objected to because of the following informality: Claim 20, line 6, recites the phrase "selected from a group consisting of". The term "the" should be replaced with the term "a". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in

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the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

#### LACK OF WRITTEN DESCRIPTION

Claim 29 recites that a central processing unit “executes DISTANCE program”. The specification states that a “specially developed program ‘DISTANCE’ was used for computation” on page 13, first paragraph. The specification generally states that data mining software and a software copyright have been filed (page 12, first paragraph). The specification recites steps used in a computer-based method (page 13, last paragraph), examples of Input/Output format of DISTANCE (Example 1) and calculations used in the method (Examples 2-4). However, the specification does not specifically state actual computational steps of the DISTANCE program. Due to the absence of a clear disclosure of what the DISTANCE program entails, this claim lacks adequate written description.

#### LACK OF SCOPE OF ENABLEMENT

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology

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is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 20-24, 26-30, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying a candidate protein useful as an anti-infective via calculating protein sequence-based attributes *comprising* percentage of charged amino acids, percentage hydrophobicity, distance of protein sequence from a fixed reference frame, measure of dipeptide complexity, *and* measure of hydrophobicity from a fixed reference frame followed by clustering said protein sequences based on said protein sequence-based attributes, and identifying outlier proteins, does not reasonably provide enablement for identifying a candidate protein useful as an anti-infective via calculating *one or less than all* of the protein sequence-based attributes listed above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification provides full enablement for identifying a candidate protein useful as an anti-infective via calculating protein sequence-based attributes *comprising* (all of) percentage of charged amino acids, percentage hydrophobicity, distance of protein sequence from a fixed reference frame, measure of dipeptide complexity, *and* measure of hydrophobicity from a fixed reference frame followed by clustering said protein sequences based on said protein sequence-based attributes, and identifying outlier proteins, as stated on pages 9 (second full paragraph), 19 (second paragraph), and Examples 2 and 3, of the specification. The specification does not describe how one skilled in the art can identify a candidate protein useful as an anti-infective by calculating *less than all* (i.e. one “selected from [the] group consisting of”) of the above-

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mentioned protein sequence-based attributes followed by clustering and identifying outlier proteins. For example, one of skill in the art would not know how to draw conclusions about anti-infective outliers based solely on the percentage of charged amino acids, and the specification provides no working examples on this matter. One skilled in the art would not reasonably conclude that the clustering of positively or negatively charged amino acids from neutral components would be able to identify candidate proteins useful as an anti-infective. Because the examples in the specification describe how to use the complete set of protein sequence based-attributes for cluster analysis, but not how to use a single attribute type cluster analysis, there is a lack of scope of enablement.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

December 15, 2005

MARJORIE A. MORAN  
PRIMARY EXAMINER  
*Marjorie A. Moran*  
12/20/05